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K052784

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

August 10, 2005

Submitter's Information: 21 CFR 807.92(a)(1)

Ms. Bo Hyoung Kim, Director
INFINITT CO.,LTD
Taesuk Bldg. 9F, 275-5 Yangjae-Dong
Seocho-Gu, Seoul, South Korea 137-943
Fax: 82-2-2194-1688
Email: lemon@infinitt.com

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	Reformat Gateway™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Product Code:	LLZ
Classification Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Reformat Gateway™ software device is substantially equivalent to the:

Manufacturer:	Voxar Limited Bonnington Bond, 2 Anderson Place Edinburgh, UK EH6 5 NP
Device Name:	plug 'n view 3d, version 1.0
510(k) Number:	K 992654
Decision Date:	11/05/1999
Decision:	Substantially Equivalent
Panel Code reviewed by:	Radiology
Panel Code classified by:	Radiology
Product Code:	LLZ
Device Classification Name:	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number:	Class II - 892.2050

Device Description: 21 CFR 807 92(a)(4)

Reformat Gateway is a software that receives original data from several devices or PACS system, which reconstructs and sends it to other system automatically. Reformat Gateway reconstructs the thin section slice data into thick section slice data automatically for a fast and routine diagnosis. Also, it generates a MPR

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reconstructed image automatically according to data specification and distributes original data or reconstructed data to distributed different systems.

Indications for Use: 21 CFR 807 92(a)(5)

Reformat Gateway™ is a software application for the display and 3D visualization of medical data derived from digital modalities (CT and MRI scanners). It is intended for use by radiologists, clinicians and referring physicians to acquire, process, render, review, store, print, and distribute DICOM compliant image studies using standard PC hardware.

Technological Characteristics: 21 CFR 807 92(a)(6)

The proposed and predicate devices are both software programs that can be used for manipulation of DICOM-compliant images. The proposed and predicate software can be operated from a personal computer. Differences between the proposed and predicate devices are limited to the availability of certain image viewing and editing features.

The Reformat Gateway™ software conforms to DICOM (Digital Imaging and Communications in Medicine) Version 3.

Validation testing was provided that confirms that Reformat Gateway™ performs all input functions, output functions, and all required actions according to the functional requirements specified in the Software Requirements Specification (SRS).

Conclusion: 21 CFR 807 92(b)(1)

The 510 (k) Pre-Market Notification for the Reformat Gateway™ software contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The Reformat Gateway™ device has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrati
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

Infinitt Co., Ltd
% Mr. Carl Alletto
Consultant
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210

Re: K052284
Trade/Device Name: Reformat Gateway
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 1, 2005
Received: August 24, 2005

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(Indications for Use Form)

510(k) Number: K052284

Device Name: Reformat Gateway™

Indications for Use:

Reformat Gateway™ is a software application for the display and 3D visualization of medical data derived from digital modalities (CT and MRI scanners). It is intended for use by radiologists, clinicians and referring physicians to acquire, process, render, review, store, print, and distribute DICOM compliant image studies using standard PC hardware. Typical users of this system are trained professionals, i.e. physicians, radiologists, nurses, medical technicians, and assistants.

Prescription Use __√√_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

David G. Hoyum

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052284